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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,666	04/04/2006	**Mannalal Ramgopal Bajaj**	125139-00101	9001

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EXAMINER	
LEA, CHRISTOPHER RAYMOND	
ART UNIT	**PAPER NUMBER**
1619	
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12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,666	BAJAJ ET AL.	
	Examiner	Art Unit	
	Christopher R. Lea	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12 and 15-18* is/are rejected.

7)☒ Claim(s) *9,10 and 16-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/04/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/IN04/00342.

Claims 1-10, 12, & 15-18 are pending. Claims 1-10, 12, & 15-18 are under examination.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on April 4, 2006, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claims 9, 10, & 16-18 are objected to because of the following informalities:

Claim 9, line 2: The claim recites "...the said..." which is redundant. Please delete one of the words.

Claim 10, line 2: The claim recites "...the said..." which is redundant. Please delete one of the words.

Claim 16, line 1: The claim recites "...the said..." which is redundant. Please delete one of the words.

Claim 17, line 1: The claim recites "...the said..." which is redundant. Please delete one of the words.

Claim 18, lines 2 & 4: The words "Water For Injection" and "Mannitol" should not be capitalized.

Claim 18, line 11: Examiner believes the word "lounging" should be "bunging".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6, 9, 10, 16 & 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Doen et al. (US PreGrant Publication 2003/0191157).

6. Claim 1: Doen et al. disclose a composition containing a benzimidazole compound (2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfonyl]-1H-benzimidazole, referred to by Doen et al. as compound A, commonly known as lansoprazole) and an excipient (mannitol) in powder form (Example 3, Table 4, paragraph 132).

7. Claim 6: Doen et al. disclose the form of a stabilized lyophilized injection (paragraph 132).

8. Claims 9 & 16: Doen et al. disclose a composition that contains ~29% benzimidazole compound (Example 3, Table 4, paragraph 132).

Claims 10 & 17: Doen et al. disclose a composition that contains ~58% excipient (Example 3, Table 4, paragraph 132).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-5, 7, 8, 12, 15, & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doen et al. (US PreGrant Publication 2003/0191157).

Applicant claims

Applicant claims a system containing a benzimidazole compound and excipients in a lyophilized form that can redissolved for parenteral administration.

Determination of the scope and content of the prior art (MPEP 2141.01)

Doen et al. teach, as a whole, an injectable composition containing a benzimidazole.

Since claims 2-5, 7, 8, & 15 ultimately depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Doen et al. appears above.

Claims 2-4: Doen et al. teach the pharmaceutically acceptable salts of the benzimidazole include inorganic salts (paragraph 80). Among these inorganic salts are sodium, potassium, calcium, and magnesium (paragraph 81).

Claims 5 & 7: Doen et al. teach a composition containing a benzimidazole compound, mannitol, sodium hydroxide (paragraph 96). Doen et al. teach rabeprazole sodium among the benzimidazole compounds of the invention (paragraph 76). Doen et

al. teach water for injection as a solvent for redissolving the composition (paragraph 110).

Claim 8: Doen et al. teach the pH of the composition as about 9 to 11 in physiological saline (paragraph 99).

Claim 15: Doen et al. teach rabeprazole sodium among the benzimidazole compounds of the invention (paragraph 76).

Claims 18 & 12: Doen et al. teach adding a benzimidazole compound and mannitol to a sodium hydroxide solution and adding water for injection (paragraph 128, changing the order of adding ingredients is *prima facie* obvious, MPEP § 2144.04.IV.C). Doen et al. teach sterile filtering the solution (through 0.22 micron filter) and placing it in vials (paragraphs 128-9). Though Doen et al. are silent as to the exact size of the vial and its sterility, they teach the vial size is under 20 mL (paragraph 106) and it would have been obvious to a skilled artisan to put a sterile filtered solution into a sterile vial and bunging the vial to maintain sterility. Doen et al. are silent as to the temperature at which the steps are carried out; however, the maintaining a constant temperature is within the purview of the skilled artisan. Doen et al. teach lyophilizing the solution to form a powder (paragraph 132). The resultant composition meets the limitations of claim 12.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Doen et al. and the instant claims is that Doen et al. do not embody the claims with rabeprazole but with lansoprazole.

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate the compositions of Doen et al. using rabeprazole and produce the instant invention, because Doen et al. teach rabeprazole as a functional equivalent to the preferred lansoprazole as they are both known to be proton pump inhibitors. The skilled artisan would have been motivated to use rabeprazole because it would have been obvious to try the four different benzimidazole proton pump inhibitors specifically listed by Doen et al. (paragraphs 74-77) to find one that performs well and is available to market.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in substituting rabeprazole for lansoprazole and producing the claimed invention because they are both taught by Doen et al. as acceptable active agents in the composition. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-10, 12, 15-18 are rejected. Claims 9, 10, & 16-18 are objected to. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616